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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,776	07/26/2001	Hyesook Kim	3087.00005	6900

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/20/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,776

Applicant(s)

KIM ET AL.

Examiner

Sheridan K Snedden

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 14, 17-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Art Unit: 1653

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #8, filed 20 February 2003. Applicant's amendment of claims 1-3, 10 and 15 is acknowledged. Applicant's addition of new claims 34 and 35 is acknowledged. Claims 34-35 are directed to nonelected material. The election in Paper #6 was to claims 1-3, 10-13 and 15-16 and cytochrome c. Therefore, claims 34-35 are withdrawn from consideration. Claims 1-35 are pending. Claims 1-3, 10-13 and 15-16 as are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Drawings

3. The drawings are objected to for the reasons indicated on the form PTO 948 accompanying Paper #7. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

Specification

The amendment filed 20 February 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

Art Unit: 1653

supported by the original disclosure is as follows: The specification teaches the measurement of covalently polymerized proteins that necessarily includes protein aggregates, as the aggregates are polymerized by covalent thiol-crosslinking. Additionally, the claims add the limitation of *in vivo* assessments that is not taught in the specification. The specification teaches a test tube, or *in vitro*, method of measuring polymerized proteins. The specification fails to teach or provide examples for a method of measuring polymerized proteins *in vivo*, or within a living body.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 10-13 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are amended to add the limitations of excluding protein aggregates (regarding claims 1, 15 and dependent claims thereto) and *in vivo* assessments (regarding claims 1-3, 10-13 and 15-16). The specification does not teach the exclusion of protein aggregates from the measurements of polymerized proteins. The specification teaches the measurement of covalently

Art Unit: 1653

polymerized proteins that necessarily includes protein aggregates, as the aggregates are polymerized by covalent thiol-crosslinking.

Additionally, the claims add the limitation of *in vivo* assessments that is not taught in the specification. The specification teaches a test tube, or *in vitro*, method of measuring polymerized proteins. The specification fails to teach or provide examples for a method of measuring polymerized proteins *in vivo*, or within a living body.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 10-13 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 10-13 and 15-16 are indefinite. It is unclear from the recited steps as to how covalent bonds resulting from polymerized protein will be distinguish from the covalent bonds resulting from protein aggregation. Furthermore, the method seems incomplete as the expected results are not indicated. Would increased levels of oxidative stress indicate increase levels of polymerized protein?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1653

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cassina *et al.* Cassina *et al.* teach a method for assessing oxidative stress by measuring nitrated cytochrome c, obtained from an *in vivo* source. On page 21412 (first paragraph and figure 4), Cassina *et al.* teach that increased oxidative stress resulting from higher concentrations of peroxynitrite lead to the dimerization, or covalent polymerization, of nitrated cytochrome c (regarding claim 1-3 and 15-16). Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 10-13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassina *et al.* in view of Ahern (The Scientist, 1995, Vol 9, No: 15, page 20).

Cassina *et al.* teach a method for assessing oxidative stress by measuring nitrated cytochrome c, obtained from an *in vivo* source. On page 21412 (first paragraph and figure 4), Cassina *et al.* teach that increased oxidative stress resulting from higher concentrations of peroxynitrite lead to the dimerization, or covalent polymerization, of nitrated cytochrome c (regarding claim 1-3 and 15-16). As indicated in the method steps producing the results of figure 4, Cassina *et al.* performed SDS-PAGE and western blot analysis to determine the extent of nitration and polymerization (regarding claims 10-13).

Art Unit: 1653

Ahern teach the benefits of an assay kit. Ahern teach that providing reagents and method step in a ready made kit allowed scientist to save time and money, especially when conducting standard lab protocols.

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to supply the materials and instructions of the method taught by Cassina *et al.* The person of ordinary skill in the art would have been motivated to prepare a kit in order to save time and money. The person of ordinary skill in the art would have expected success in preparing the kit as the steps performed and materials utilized are standard in the art. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Applicant's comments in the response have been considered as to the newly made grounds of rejection under USC 102 and 103 but are unpersuasive for the reasons stated in the grounds of rejection.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for

Application/Control Number: 09/915,776

Page 7

Art Unit: 1653

regular communications to the organization where this application or proceeding is assigned is
(703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding
should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

May 19, 2003

SKS

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600